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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/698,148
Filing Date: October 31, 2003
Appellant(s): KAGAN ET AL.

Kagan et al.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8/26/2010 appealing from the Office action mailed 7/9/2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 43-50, 52, 54-61, 72, and 73 are pending and rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 43-50, 52, 54-61 and 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler (U.S. Application Number 2004/0039452 A1) in view of Taylor (U.S. Patent 6,254,642) in further view of Moss (U.S. Patent 5,470,337).

Bessler discloses an endoscopic gastric bypass device and methods (figures 1-4). Bessler discloses a method for treating obesity with the steps of providing a gastric sleeve (figure 4) with a proximal end (42), distal end (44), and lumen extending threrethrough (40), transesophageally advancing the sleeve adjacent an attachment site

near the gastroesophageal junction (near 60), advancing the proximal end through the stomach and into the intestines or beyond, and attaching the proximal end at the attachment site to deliver food from the esophagus directly into the intestine (see paragraphs [0012]-[0027]). Bessler discloses a support tissue anchor tubular cuff, at the site of attachment, (42), and extending the sleeve (40) distally of duodenum or beyond (paragraph [0020]. Further Bessler discloses that the length of the tube sleeve could be up to 250cm or beyond in length [0020] and permanently attached to the cuff. The Bessler device is fully capable of being sufficiently flexible that the material traveling through the sleeve is influenced by the natural operation of the pyloris.

Bessler discloses the claimed invention except for the attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface. Taylor teaches that it is known to use attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface, (as set forth in paragraphs at columns 7-9, and shown in figures 6a-6E) to provide an efficient low profile anchoring system with a size that resists cutting or tearing of tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as

taught by Bessler with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface as taught by Taylor, since such a modification would provide the method with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface for providing an efficient low profile anchoring system with a size that resists cutting or tearing of tissue (column 11 lines 14-25). Concerning the claim language of "without creating a serosal to serosal bond" it is examiners position that the type of attachment depicted in figures 6a-6e would not create a serosal to serosal bond.

Moss teaches surgical fasteners for securing a hollow organ or device to an outer tissue layer with a first and second opposing fastener heads which change from a transversely reduced configuration while passing transmurally through a site to a transversely enlarged configuration after passing through the site and further wherein the enlarged configuration of the tissue anchor is transversely larger than any transverse portion of the tissue anchor when the tissue anchor is passing transmurally through the attachment site in a reduced configuration (see figures 3, 4, and 7).

Bessler in view of Taylor discloses the claimed invention except for the specific fastening anchors which transversally are reduced while passing and transversally enlarged after. Moss teaches that it is known to use specific fastening anchors which transversally are reduced while passing and transversally enlarged after as set forth in paragraphs at columns 3-6 to provide a means for tissue anchoring which substantially

eliminates ancillary tissue damage and inacurate placement. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Bessler in view of Taylor with specific fastening anchors which transversally are reduced while passing and transversally enlarged after as taught by Moss, since such a modification would provide the method with specific fastening anchors which transversally are reduced while passing and transversally enlarged after for providing a means for tissue anchoring which substantially eliminates ancillary tissue damage and inacurate placement.

Claims 43-50, 52, 54-61 and 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gannoe et al. (U.S. Application Number 2004/0082963 A1) in view of Taylor (U.S. Patent 6,254,642) in further view of Moss (U.S. Patent 5,470,337).

Gannoe discloses a method and device for use in endoscopic organ procedures. Gannoe discloses a method for treating obesity and providing a lengthy sleeve and support tissue anchor with a temp or permanent cuff by suture transesophageally to an attachment site near the gastroesophageal junction, with a proximal and distal ends, where the distal end can extend into the intestines or beyond (See paragraph [0035]). The attachment site support may be implanted with or without the sleeve (see figure 5A-5E, specifically 5E). The Gannoe device is fully capable of being sufficiently flexible that the material traveling through the sleeve is influenced by the natural operation of the pyloris.

Gannoe discloses the claimed invention except for the attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface. Taylor teaches that it is known to use attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface, (as set forth in paragraphs at columns 7-9, and shown in figures 6a-6E) to provide an efficient low profile anchoring system with a size that resists cutting or tearing of tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Gannoe with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface as taught by Taylor, since such a modification would provide the method with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface for providing an efficient low profile anchoring system with a size that resists cutting or tearing of tissue (column 11 lines 14-25).

Moss teaches surgical fasteners for securing a hollow organ or device to an outer tissue layer with a first and second opposing fastener heads which change from a

transversely reduced configuration while passing transmurally through a site to a transversely enlarged configuration after passing through the site and further wherein the enlarged configuration of the tissue anchor is transversely larger than any transverse portion of the tissue anchor when the tissue anchor is passing transmurally through the attachment site in a reduced configuration (see figures 3, 4, and 7).

Gannoe in view of Taylor discloses the claimed invention except for the specific fastening anchors which transversally are reduced while passing and transversally enlarged after. Moss teaches that it is known to use specific fastening anchors which transversally are reduced while passing and transversally enlarged after as set forth in paragraphs at columns 3-6 to provide a means for tissue anchoring which substantially eliminates ancillary tissue damage and inacurate placement. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Gannoe in view of Taylor with specific fastening anchors which transversally are reduced while passing and transversally enlarged after as taught by Moss, since such a modification would provide the method with specific fastening anchors which transversally are reduced while passing and transversally enlarged after for providing a means for tissue anchoring which substantially eliminates ancillary tissue damage and inacurate placement.

Claims 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler in view of Taylor in further view of Moss or Gannoe in view of Taylor in further view of Moss. Both references disclose the method claimed except for the specifics of

the tissue anchor. Both Bessler in view of Taylor or Gannoe in view of Taylor discloses the claimed invention except for transmurally implanting a "T-tag" to attach the cuff. It would have been obvious to one having ordinary skill in the art at the time the invention was made to transmurally implanting a "T-tag" to attach a cuff, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).* The use of the "T-tag" is simply a preferred type of fastener, Gannoe specifically teaches using staples or sutures to attach to a site. It would have been obvious to use a "T-tag" as a preferred type of fastener to securely attach the cuff to the site.

(10) Response to Argument

The Appellant's primary argument is directed towards the rejection of claims 43-50, 52, 54-61, 71, and 73 would not have been obvious over Bessler in view of Taylor, and further in view of Moss or alternately Gannoe in view of Taylor, and further in view of Moss. Appellants argue that one of ordinary skill would have no reason to combine the references, no reasonable expectation of success in the combination, there are secondary considerations support a finding of non-obviousness (teaching away, Failure of others/unexpected results), and the examiner must give proper weight to the Thompson Declaration.

It is examiners position simply that both Bessler or Gannoe teach the method of treating a patient with the "providing a gastrointestinal sleeve" step, "transesophageally

advancing" step and "advancing the distal end" step; Taylor teaches the attachment step/type, and Moss teaches the exact type of barb or tag to attach it with. Examiner is relying on Taylor to teach that it is known in the art and an obvious modification to use an "attachment" step that does not create a serosal to serosal bond that goes directly through the tissue (rather then create a serosal to serosal fold as in Gannoe or an expandable stent of Bessler). Finally examiner is relying on Moss for the showing that instead of a straight barb, one could alternatively use a penetrating/t-tag type anchor barb.

Specifically the claims are directed to "a method of treating a patient", obesity is not part of the claims. It is examiners position that all the references are for treating a patient and attempt to treat or solve a related problem. Gannoe and Bessler are for treating obesity in a patient, and Taylor is for treating Gastroesophageal reflux disease in a patient. All the references methods and devices are attached at or near the Gastroesophgeal junction (GEJ). Moss is simply a type of barb or attachment anchor that is a specific type (transmurally/transverselly enlarged) of the general one of Taylor. Moss anchor would be a more secure, easily attached, and permanent type of anchor then that of Taylors simple anchors.

Although Gannoe and Bessler each teach an alternate means of attaching a sleeve to the GEJ area (Gannoe by serosal to serosal fold and Bessler by expandible stent), it is well known in the art as an alternate means of "attaching" a tube/sleeve like structure near the GEJ area is by going through the tissue directly as taught by Taylor (fig 6d). This type of attachment would provide (and one would expect) a more stable

and permanent "attachment" or fixing of the device to the patient at the GEJ. It is examiners positon that one skilled in the art and wishing to secure a sleeve within the patient near the GEJ would know that you could attach it by expansion (bessler), serosal to serosal folding attachment (Gannoe) or simply by going directly through the tissue (as in Taylor figure 6D). It is examiners position that the reason one would combine the prior art references of Gannoe/or Bessler with Taylor is that Taylor teaches a alternate known type of attachment that is more permanent and quicker in attachment then the Gannoe or Bessler types of attachment. One would also look to the transmurally attachment tags of Moss as an alternate to the barbs of Taylor to provide a more permanent, secure, and easily attaching anchor then the example ones of Taylor.

Examiner is of the position that one would have a reasonable expectation of success in the combination of references. As stated above Taylor in figure 6d shows a barb going directly through the tissue (not a serosal to serosal bond), and it appears that they are connecting a tube sleeve within a patient (at or near the GEJ) by that barbed attachment. Although a different and more direct type of attachment, examiner is of the position that Taylors attachment is of consistent with the operation and function of the attachments of Gannoe or Bessler. The Taylor sleeve tube is similar in form and structure to that of Gannoe or Bessler sleeve tube and therefore the examiner would have a reasonable expectation of success in the combination.

Examiner is of the position that Secondary Considerations (teaching away, failure of others/unexpected results, ect.) have been considered and analyzed, however they failed to rebut that the art taught away from such a combination of obviousness. Simply

that there are differences between two references is insufficient to establish that such references "teach away" from any combination thereof. Although Bessler states that it uses an expandible stent no where in the reference states that one could not use any other type of attachment or explicitly states that one shouldn't use a direct barb attachment like Taylor/Moss. Concerning the failure of others/unexpected results argument by the Appellant, Examiner has considered and weight the disclosure of the "Thompson Declaration" regarding the time, money effort and problems overcome however this evidence does not outweigh the disclosure of Taylor as to viable means of attaching a tube sheath near the GEJ. Therefore it is examiners position that the fact that other failed/unexpected results and the statements made in the Thompson Declaration is not sufficient to overcome the obvious rejection of the prior art when the taken as a whole. The Thompson reference makes various "opinion" testimony and statments personal of why "he" would or wouldn't do something but gives little facts and standards as to what is the level of skill in the industry at the time of the invention. The examiner has given weight to the Thompson Declaration but is not of the opinion that it overcomes the rejection as currently made.

In conclusion the examiners position is that one would find the applicant's claims obvious when modifying Bessler (or Gannoe) in view of Taylor and further in view of Moss. Examiner is rely on the disclosure of the how to attach a sleeve tube in Taylor (and Moss) as an obvious modification of Bessler and Gannoe, All these devices are used in in the same anatomical region (Near GEJ) and with similar structures and functions (used to bypass or isolate regions in the esophageal-gastointestinal tract),

therefore one would find obvious to combine these and expect successes in the one one translate to success in the combination, (combining a similar sleeve by a known attachment alternative would lead to a successful combination). Further the Secondary factors (teach away, failure of other/unexpected results, Thompson Declaration), fail to overcome the disclosure of the prior art when taken as a whole and the obvious rejection made. Therefore examiner is maintaining the rejection as proper.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Phillip Gray/

Examiner, Art Unit 3767

Conferees:

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767

/Sue Lao/

Primary Examiner